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MAY 07 2014

510(k) Summary: K132870

510(k) Summary in accordance with the requirements of 21 CFR 807.92

This 510(k) Summary is submitted in accordance with the requirements of 21 CFR Part 807, Section 807.92(c).

Submitter: Origio Inc.
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Date Prepared: April, 24 2014

Device Information

Trade Name:	Origio Gas Line Filter
Common/Usual Name:	Gas Line Filter
Classification:	Class II
Classification Panel:	Obstetrics/Gynecology
Regulation Number:	21 CFR 884.6120
Regulation Name:	Accessories, Assisted Reproduction
Product Code:	MQG

Predicate Device

Origio has compared the Origio Gas Line Filter to the CODA Inline Filter, which was included as part of 510(k) K001486 for the <genX> CODA Air Purification System, submitted by <genX> International Company.

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Device Description

The Origio Gas Line Filter combines a High Efficiency Particulate Air (HEPA) Filter Media and an Activated Carbon Media Filter which is impregnated with Potassium Permanganate ($KMNO_4$). The 1.5", 0.5µm Glass Fiber HEPA Media is designed to remove particulates from the supply gas, N_2, CO_2 or TriGas (N_2, CO_2 and O_2) blend which is commonly used in IVF Incubators and other IVF work stations. The 3.5" Potassium Permanganate – Impregnated Activated Carbon Fiber Felt Media is designed to remove Volatile Organic Compounds (VOC's) from the supply gas provided to the IVF Incubator/Work Station.

The HEPA Filter Media and the Activated Carbon Filter Media are encased in a polypropylene outer shell creating a capsule for the filtration of the medical supply gas. The Origio Gas Line Filter is designed to be installed between the supply gas and the IVF Incubator/Work station utilizing the integrated ¼" male and ¼" female quick- connections. Quick disconnect "intake and output fittings" and clamps are provided along with a magnetic holding bracket for easy installation on to the supply gas line. The Origio Gas Line Filter is provided non-sterile and is individually vacuum packed in a double poly bag.

Indication for Use

The Origio Gas Line Filter is intended for the reduction of volatile organic compounds (VOC's), and particulate contaminants from supply gas lines to incubators and work stations that are used in assisted reproduction technologies and/or In vitro fertilization procedures.

Technological Characteristics Comparison

The materials of construction and design features of the Origio Gas Line Filter are very similar to the predicate Coda InLine filter. The capsule size for both filters are also comparable in that the Origio Filter has a 5 ½ inch long capsule and the Coda InLine Filter capsule is approximately 6½ inches long. Each filter is designed with integral ¼ inch male and female quick disconnect features to enable easy installation on to the supply gas line.

Each filter has an activated carbon filter component and a HEPA filter media component contained in a capsule that is placed on the gas line supplying N_2, CO_2 or TriGas (N_2, CO_2 and O_2) blend. The main difference between the Origio filter and the predicate CODA filter is the addition of potassium permanganate ($KMNO_4$), which is impregnated into the rolled activated carbon fiber felt component contained in the Origio Gas Line Filter, as an additional measure to reduce VOC's which can be found in the supply gas lines.

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The activated carbon and the potassium permanganate contained in the Origio Gas Line Filter are not loose or granulated and do not pass through the secondary particle filter. The particle filtration testing conducted has demonstrated that this secondary filter meets ULPA efficiency requirements. Additionally, there were no toxic effects observed with cultured embryos while using the Origio Gas Line Filters on the incubation system utilized for Mouse Embryo Assay testing. Therefore, we believe the use of the potassium permanganate within the Activated Carbon filter component of the Origio Gas Line Filter does not pose additional safety or effectiveness questions as compared to the predicate device.

While there are differences in the construction and materials of the capsule filter with respect to the HEPA/ULPA filter and the activated carbon (Granulated Activated Carbon for the CODA Filter vs. Rolled Carbon fiber felt/with impregnated $KMNO_4$ for the Origio Filter), the intended purpose of these filtering components are the same, which is to remove VOC's, and particulate contaminants from the supply gas. Both the Origio Gas Line Filter and the predicate Coda InLine Filter are used in the same manner and for the same intended purpose as an accessory to the IVF incubator system and/or workstation by filtering VOC's and particulate contaminants from the supply gas lines, which are used in assisted reproduction technologies and/or In vitro fertilization procedures.

Comparison of Key Design Features and Characteristics

Device Name	**Origio Gas Line Filter**	**(CODA InLine Filter)**
510(k) Number	Subject 510(k)	K001486 **<genX> CODA Air Purification System**
Indication for Use	The Origio Gas Line Filter is intended for the reduction of volatile organic compounds (VOC's), and particulate contaminants from supply gas lines to incubators and work stations that are used in assisted reproduction technologies and/or In vitro fertilization procedures.	The CODA Air Purification System will be used as an accessory during assisted reproductive procedures.
Target Population	Embryologists in IVF and ART Laboratories	Embryologists in IVF and ART Laboratories
Device Characteristics and Design Features		
Gas Line Connection Features	Includes ¼" male and female quick disconnect features on proximal and distal end of capsule.	Includes ¼" male and female quick disconnect features on proximal and distal end of capsule.
Installation	Filter placement between supply gas and incubator using supplied standard ¼" male and female quick connect fittings and holding bracket.	Filter placement between supply gas and incubator using supplied standard ¼" male and female quick connect fittings and holding bracket.

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"Use Life" – Frequency of filter change	Up to 6 months	2 months
Shelf Life	3 years	No Information Available
Filtration Efficiency	HEPA filter must capture a minimum of 99.97% of particulate contaminants at 0.3 microns in size. Actual Efficiency – The Origio Filter meets requirements for both ULPA (Ultra Low Penetration Air) and HEPA (High Efficiency Particulate Air) with ≥ 99.999 % efficiency for particle sizes between 0.1-0.2 microns and 0.2-0.3 microns throughout the 3 year shelf life. Use Life of up to 6 months was demonstrated with filtration efficiencies meeting both ULPA and HEPA requirements for filters challenged with a worse case particle load simulating 6 months of usage in an IVF Lab.	HEPA filter must capture a minimum of 99.97% of particulate contaminants at 0.3 microns in size. Actual Efficiency – Unknown
VOC Removal Efficiency	Testing demonstrates >99% efficiency up to a 6 month "use life".	Actual VOC Efficiency - Unknown
Materials of Construction		
Capsule Material/Size	Polypropylene (Shell) ~5 ½ inches	Molded Plastic (Shell) ~6½ inches (Material Unknown)
HEPA/ULPA Filter	Microglass Fiber Media	HEPA Filter Media (Unknown)
Activated Carbon Filter Media Component	Activated Carbon Fiber Felt Media (rolled), impregnated with potassium permanganate ($KMNO_4$)	Activated Carbon Media (Loose/Granulated)
Sterilization and Packaging		
Sterilization	Filter is provided non-sterile	Filter is not labeled as sterile.
Packaging Materials	Vacuum sealed in a double layer Polyethylene bag with Corrugated outer box.	Vacuum sealed in a single layer plastic bag with corrugated outer box.
Labeling	Includes flow direction markings molded into capsule as well as included on labelling.	Includes flow direction markings on labelling.

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Performance Testing and Safety

Performance testing was conducted on the Origio Gas Line Filter demonstrating the overall structural integrity, filtration efficiency and the effectiveness in the reduction/removal of Volatile Organic Compounds. Structural integrity testing included the following: Flow Rate and Pressure Drop, Diffusion and Bubble Point and Burst Pressure.

Particle filtration efficiency testing was conducted using an industry standard test method to demonstrate the filters met HEPA and ULPA requirements. Particle filtration efficiency was conducted with new filters, aged filters and filters that were challenged with a simulated particle load representing 6 months of use life based upon reported "source air" particle levels found in typical IVF Laboratories.

VOC removal efficiency testing was performed using a challenge supply gas concentration containing 17 different VOCs based upon the published literature for the reported VOC levels found in the typical IVF Laboratory. VOC removal efficiency values for the Origio Gas Line Filter was demonstrated up to the 6-month use life for new and aged filters. Additional VOC efficiency testing was conducted confirming that filters which had already been in service in IVF laboratories for 6 months were still effective in removing VOC's at the end of their actual "Use Life".

Mouse Embryo Assay testing of the Origio Gas Line Filter was conducted with the Origio Gas Line Filter installed on the incubator gas supply line to provide verification that the use of Origio Gas Line Filter does not negatively impact or effect mouse embryo development.

Conclusion

Based on our performance testing and the assessment of the similarities and differences between the Origio Gas Line Filter and the predicate Coda Inline Filter, Origio believes the Origio Gas Line Filter is substantially equivalent with respect to the fundamental scientific technology, materials of construction, design features, filtration efficiency, VOC removal capabilities and intended use as compared to the predicate device "Coda InLine Filter", that was previously cleared under K001486, <genX> CODA Air Purification System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 7, 2014

Origio, Inc.
John Clay
Director of Regulatory Affairs
2400 Hunters Way
Charlottesville, VA 22911

Re: K132870
Trade/Device Name: ORIGIO® Gas Line Filter
Regulation Number: 21 CFR§ 884.6120
Regulation Name: Assisted reproduction accessories
Regulatory Class: II
Product Code: MQG
Dated: March 27, 2014
Received: March 31, 2014

Dear John Clay,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132870

Device Name
ORIGIO® Gas Line Filter

Indications for Use *(Describe)*
The ORIGIO® Gas Line Filter is intended for the reduction of volatile organic compounds (VOC's) and particulate contaminants from supply gas lines to incubators and work stations that are used in assisted reproduction technologies and/or In vitro fertilization procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Herbert P. Lerner -S
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